

Global Clinical Operations- Clinical Research Associate

Job ID
REQ-10061896

9月 11, 2025

China

摘要

监控与临床研究网站和临床试验参与相关的患者数据和学习相关信息。确保调查员遵守研究协议、法规要求和良好临床实践,并为数据验证计划提供投入。提供及时和准确的监测患者数据和研究相关信息,从源文件,研究记录和现场访问(如果适用。)可以监控学习地点和审计设施的选择。

About the Role

Key responsibilities:

- Frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on milestone and deliverables with true ownership mindset
- Manages assigned study sites, conducting phase I-IV protocols according to the Monitoring Plan and Novartis procedures
- Performs Site Initiation Visit, ensures site personnel is fully trained on all trial related aspects. Performs continuous training for amendments and new site personnel as required. Re-trains

site personnel as appropriate

- Conducts continuous site monitoring activities (onsite and remote). Implements site management activities to ensure compliance with protocol, ICH/GCP, global and local regulation including Health Authorities, IRB/EC, data privacy requirements, global and local processes as applicable. Documentation according to GDP and Novartis standards.
 - Identifies deficiencies in site processes and monitor site processes performed outside the site, works in close collaboration with site on risks mitigation and process improvements
 - Promotes a compliance culture advocating adherence to highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
 - Identify deficiencies in site process, work in close collaboration with site on risk mitigation
 - Establish a strong partnership and true collaboration with the site, to increase patient density and decrease issues at site.
 - Early engagement with site on patient inventory and patient flow in advance of SIV in close collaboration with global and local study team
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- Performs Site Closeout activities per SOPs and applicable regulations to ensure that site is aware of any follow up activity and archiving requirements
 - Attends onboarding-, disease indication and project specific training and general CRA training as required
 - Proactively collaborates with the SSO Clinical Project Manager (CPM) and CRA Manager as well as MSL, CRMA and medical advisor to ensure optimal recruitment, site development and data quality
 - Ensures that relevant site insights are shared with internal stakeholders such as site partnership manager, medical advisor, MSL and CRMA etc. to improve one Novartis approach to sites
 - Participates in audit organization and inspection readiness activities for monitoring and site related activities as required and ensures implementation of corrective actions within specified timelines
 - Collaborates with internal stakeholders and site personnel to manage data query resolution process and to ensure timely and accurate data entry
 - Ensures the site Investigator Folder is up to date. Responsible for collecting essential documents from site and accountable to keep sTMF(s) up to date

Essential requirements:

- Degree in scientific or healthcare discipline (or, for United States: 4-year degree plus relevant, related healthcare experience).
- Fluent in both written and spoken English and country language
- Up to 2 years pharmaceutical industry experience or other relevant experience
- Central/in-house monitoring or field monitoring experience is desirable

Desirable requirements:

- Decision capability
- Excellent time management and organization capabilities, including ability to prioritize and multi-task
- Risk based mindset (from issue management to risk identification) supported by Novartis

systems

- Early adopter and open mindset across borders to support one study approach
- Good knowledge of drug development process specifically clinical trial/research
- Clinical and therapeutic knowledge
- Knowledge of international standards (GCP/ICH, FDA, EMA)
- Understanding the purpose of the CRA (Patient Safety; Data Integrity; PI oversight; GCP/ICH & Protocol Compliance)

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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部门

Development

Business Unit

Innovative Medicines

地点

China

站点

Shanghai (Shanghai)

Company / Legal Entity

CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
正式

Shift Work
No

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diversityandincl.china@novartis.com 告知您的需求和 联 系方式 , 并在 邮 件中附上您的 职 位申 请编
号。



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